REMARKS

Claims 23-52 are presently pending in the case. Claims 1-22 have been cancelled hereby. The new claims are supported by the specification and claims as originally filed. The claims correspond to claims that were pending in the parent application.

Consideration of the present case in view of the amendments herein is requested.

Claim rejections under judicially created doctrine of Double Patenting

The Examiner rejected claims 33-37 and 47-52 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent 6,655,379.

To expedite prosecution of the present case, Applicant submits herewith a terminal disclaimer in compliance with 37 CFR 1.321(c) in accordance with the Examiner's suggestion. It is requested that the double patenting rejection be removed in view of this disclaimer.

Double Patenting

The Examiner also rejected claims 23-32 and 38-46 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 and 12-20 of U.S. Patent 6,655,379. The rejection is traversed.

It is believed that the claims that were published by the Patent and Trademark Office in 6,655,379 are not the claims that were intended to be published. As a review of the file history of 6,655,379 reveals, the following claims were allowed and intended to be printed in 6,655,379 (as numbered during pendancy):

> 11. A device for increasing the bioavailability of an aerosolized active agent, said device comprising a flow restrictor which provides a variable flow resistance for limiting the flow of an aerosolized active agent formulation to a human patient to less than 17 liters per minute, wherein the device is adapted to aerosolize the active agent formulation and wherein the active agent formulation is (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized, or (iii) suspended or dissolved in a propellant.
>
> 12. The device of claim 11 wherein the flow restrictor comprises an orifice.
>
> 13. The device of claim 12 wherein the flow restrictor comprises apertures of 0.5 to 0.9 mm in diameter.

14. A device for delivering an active agent to the lungs of a human patient, said device comprising a flow restrictor for limiting the flow of an aerosolized active agent formulation, wherein the flow restrictor is a valve that varies the flow resistance to limit the flow to a rate less than 17 liters per minute.

15. The device of claim 11 wherein the flow restrictor is a valve that provides for decreasing resistance with increasing flow rate.

16. The device of claim 11 wherein the flow restrictor is a valve that provides for high resistance at all flow rates except a desired flow rate range.

17. The device of claim 11 wherein the device is adapted to be used with an active agent selected from the group consisting of insulin, cyclosporin, parathyroid hormone, follicle stimulating hormone, alpha-1-antitrypsin, budesonide, human growth hormone, growth hormone releasing hormone, interferon alpha, interferon beta, growth colony stimulating factor, leutinizing hormone releasing hormone, calcitonin, low molecular weight heparin, somatostatin, respiratory syncytial virus antibody, erythropoietin, Factor VIII, Factor IX, ceredase, cerezyme and analogues, agonists and antagonists thereof.

21. A device for delivering aerosolized insulin to the lungs of a human patient, wherein said device comprises a flow restrictor which provides a variable flow resistance to restrict an inspiratory flow rate of an aerosolized insulin formulation to less than 17 liters per minute and wherein the device is adapted to aerosolize the insulin.

22. The device of claim 21 wherein the flow restrictor provides a variable flow resistance to restrict the inspiratory flow rate to 10 liters per minute or less.

23. The device of claim 11 wherein the active agent formulation is a powder and wherein the device is adapted to aerosolize the active agent formulation.

24. The device of claim 11 wherein the active agent formulation is contained in a blister and wherein the device is adapted to receive the blister.

27. The device of claim 21 wherein the active agent formulation is a powder and wherein the device is adapted to aerosolize the active agent formulation.

28. The device of claim 21 wherein the active agent formulation is contained in a blister and wherein the device is adapted to receive the blister.

29. A device for delivering an aerosolized active agent to the lungs of a human patient, wherein said device comprises an orifice that varies in size so that an aerosolized active agent formulation may be delivered at an inspiratory flow rate of less than 17 liters per minute, wherein the device is adapted to aerosolize the active agent formulation and wherein the active agent formulation is (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized, or (iii) suspended or dissolved in a propellant.

30. The device of claim 29 wherein the device is adapted to deliver an aerosolized insulin formulation to the lungs.

31. The device of claim 29 wherein the orifice varies in size so that the aerosolized active agent formulation may be delivered at an inspiratory flow rate of 10 liters per minute or less.

32. The device of claim 29 wherein the active agent formulation is a powder and wherein the device is adapted to aerosolize the active agent formulation.

33. The device of claim 29 wherein the active agent formulation is contained in a blister and wherein the device is adapted to receive the blister.

34. A device for delivering an aerosolized active agent to the lungs of a human patient, said device comprising:

a chamber in flow communication with a mouthpiece;

means for aerosolizing the active agent; and

means for varying the flow resistance to limit an inspiratory flow rate through the mouthpiece to less than 17 liters per minute,

whereby an aerosolized active agent formulation in the chamber may be delivered to the human patient, the active agent formulation being (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized, or (iii) suspended or dissolved in a propellant.

35. The device of claim 34 wherein the inspiratory flow rate is limited to 10 liters per minute or less.

36. The device of claim 34 wherein the device is adapted to deliver an aerosolized insulin formulation to the lungs.

38. The device of claim 34 wherein the active agent formulation is a powder and wherein the device is adapted to aerosolize the active agent formulation.

39. The device of claim 34 wherein the active agent formulation is contained in a blister and wherein the device is adapted to receive the blister.

40. The device of claim 11 wherein the device is adapted to aerosolize a powder active agent formulation.

41. The device of claim 40 wherein the device is adapted to aerosolize the powder active agent formulation using compressed air.

As can be seen, the presently pending claims are not identical to the allowed claims in 6,655,379. Accordingly, Applicant requests withdrawal of the rejection under 35 U.S.C. 101.

Applicant is in the process of correcting the printing error in the 6,655,379 patent.

Conclusion

Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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